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JC03 Rec'd PCT/PTO 1 2 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Shunsuke ISHII et al.

Group Art Unit : Not Yet Assigned

Appl. No. : 10/533,078

(U.S. National Stage of PCT/JP03/013855)

I.A. Filed : October 29, 2003

Examiner : Not Yet Assigned

For : PRODUCTION OF KNOCKDOWN ANIMAL VIA INTRODUCTION  
OF DOUBLE-STRANDED EXPRESSION VECTOR



### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop AMENDMENT  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir :

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicant hereby brings the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification, the International Search Report, and the International Preliminary Examination Report issued in connection with International Patent Application No. PCT/JP03/013855, of which the present application is the U.S. National Stage Application. Copies of the International Search Report in English and the International Preliminary Examination Report in English were enclosed with the papers when entering the National Stage on April 28, 2005. A copy of the International Preliminary Report on Patentability in English is enclosed herewith, as well as copies of the documents cited therein. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the

documents cited therein. The following is a list of the documents cited in the above-noted documents:

CAPECCHI et al., "Altering the Genome by Homologous Recombination", Science, Vol. 244, pp. 1288-1292 (1989). Applicants note that this document is cited on page 1 of the specification of the present application;

HANNON, "RNA Interference", Nature, Vol. 418, pp. 244-251 (2002). Applicants note that this document is cited on page 2 of the specification of the present application;

ELBASHIR et al., "duplexes of 21-nucleotide RNAs Mediate RNA Interference in Cultured Mammalian Cells", Nature, Vol. 411, pp. 494-498 (2001). Applicants note that this document is cited on page 2 of the specification of the present application;

TUSCHL et al., "Expanding Small RNA Interference", Nature Biotechnology, Vol. 20, pp. 446-448 (2002). Applicants note that this document is cited on page 2 of the specification of the present application;

MIYAGASHI et al., "U6 promoter-driven siRNAs with four uridine 3' overhangs efficiently suppress targeted gene expression in mammalian cells", Nature Biotechnology, Vol. 20, pp. 497-500 (2002). Applicants note that this document is cited on page 2 of the specification of the present application;

XIA et al., "siRNA-mediated gene silencing *in vitro* and *in vivo*", Nature Biotechnology, Vol. 20, No. 10, pp. 1006-1010 (2002);

HUANG et al., "Role of polyadenylation in nucleocytoplasmic transport of mRNA", Molecular and Cellular Biology, Vol. 16, No. 4, pp. 1534-1542 (1996). Applicants note that this document is cited on pages 13, 14, and 18 of the specification of the present application.

McKENDRICK et al., "Interaction of eukaryotic translation initiation factor 4G with the nuclear Cap-Binding Complex provides a link between Nuclear and Cytoplasmic functions of the m<sup>7</sup> Guanosine Cap", *Molecular and Cellular Biology*, Vol. 21, No. 11, pp. 3632-3641 (2001). Applicants note that this document is cited on page 13 of the specification of the present application.

YONAHHA et al., "Transcriptional termination and coupled polyadenylation *in vitro*", *The EMBO Journal*, Vol. 19, No. 14, pp. 3770-3777 (2000). Applicants note that this document is cited on page 14 of the specification of the present application.

ZENG et al., "RNA interference in human cells is restricted to the cytoplasm", *RNA*, Vol. 8, No. 7, pp. 855-860 (2002);

LEE et al., "The nuclear RNase III Drosha initiates microRNA processing", *Nature*, Vol. 425, No. 6956, pp. 415-419 (2003);

PAPP et al., "Evidence for Nuclear Processing of Plant Micro RNA and Short Interfering RNA Precursors", *Plant Physiology*, Vol. 132, No. 3, pp. 1382-1390 (2003);

SHINAGAWA et al., "Generation of *Ski*-knockdown mice by expressing a long double-strand RNA from an RNA polymerase II promoter", *Genes & Development*, Vol. 17, No. 11, pp. 1340-1345 (2003);

International Patent Publication No. WO 99/32619. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 99/49029. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 00/44895. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 01/29058. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 01/36646. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 01/42443;

International Patent Publication No. WO 01/68836;

International Patent Publication No. WO01/75164. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 02/44321. Applicants note that this document is cited on page 2 of the specification of the present application;

International Patent Publication No. WO 94/22488;

McCAFFREY et al., "RNA interference in adult mice", Nature, Vol. 418, pp. 38-39 (2002). Applicants note that this document is cited on page 2 of the specification of the present application;

HASUWA et al., "Small interfering RNA and gene silencing in transgenic mice and rats", FEBS Letters, Vol. 532, pp. 227-230 (2002). Applicants note that this document is cited on page 2 of the specification of the present application; and

KAUFMAN, "Double-stranded RNA-activated protein kinase mediates virus-induced apoptosis: A new role for an old actor", Proc. Natl. Acad. Sci., Vol. 96, No. 21, pp. 11693-11695 (1999). Applicants note that this document is cited on page 3 of the specification of the present application.

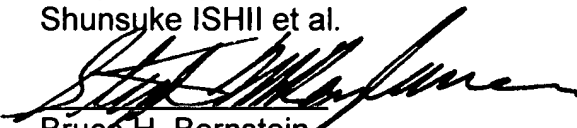
Copies of the above-noted documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of

these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material.

Should there be any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Shunsuke ISHII et al.



Bruce H. Bernstein  
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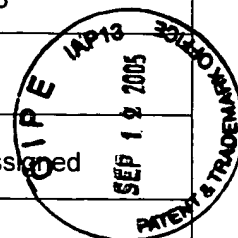
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FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P27813Application No.  
10/533,078INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)

Applicant  
Shunsuke ISHII et al.Filing Date  
October 29, 2003Group  
Not Yet Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	CAPECCHI et al., "Altering the Genome by Homologous Recombination", Science, Vol. 244, pp. 1288-1292 (1989).
2	HANNON, "RNA Interference", Nature, Vol. 418, pp. 244-251 (2002).
3	ELBASHIR et al., "duplexes of 21-nucleotide RNAs Mediate RNA Interference in Cultured Mammalian Cells", Nature, Vol. 411, pp. 494-498 (2001).
4	TUSCHL et al., "Expanding Small RNA Interference", Nature Biotechnology, Vol. 20, pp. 446-448 (2002).
5	MIYAGASHI et al., "U6 promoter-driven siRNAs with four uridine 3' overhangs efficiently suppress targeted gene expression in mammalian cells", Nature Biotechnology, Vol. 20, pp. 497-500 (2002).
6	XIA et al., "siRNA-mediated gene silencing <i>in vitro</i> and <i>in vivo</i> ", Nature Biotechnology, Vol. 20, No. 10, pp. 1006-1010 (2002).
7	HUANG et al., "Role of polyadenylation in nucleocytoplasmic transport of mRNA", Molecular and Cellular Biology, Vol. 16, No. 4, pp. 1534-1542 (1996).
8	McKENDRICK et al., "Interaction of eukaryotic translation initiation factor 4G with the nuclear Cap-Binding Complex provides a link between Nuclear and Cytoplasmic functions of the m <sup>7</sup> Guanosine Cap", Molecular and Cellular Biology, Vol. 21, No. 11, pp. 3632-3641 (2001).
9	YONAHARA et al., "Transcriptional termination and coupled polyadenylation <i>in vitro</i> ", The EMBO Journal, Vol. 19, No. 14, pp. 3770-3777 (2000).
10	ZENG et al., "RNA interference in human cells is restricted to the cytoplasm", RNA, Vol. 8, No. 7, pp. 855-860 (2002).
11	LEE et al., "The nuclear RNase III Drosha initiates microRNA processing", Nature, Vol. 425, No. 6956, pp. 415-419 (2003).
12	PAPP et al., "Evidence for Nuclear Processing of Plant Micro RNA and Short Interfering RNA Precursors", Plant Physiology, Vol. 132, No. 3, pp. 1382-1390 (2003).
13	SHINAGAWA et al., "Generation of <i>Ski</i> -knockdown mice by expressing a long double-strand RNA from an RNA polymerase II promoter", Genes & Development, Vol. 17, No. 11, pp. 1340-1345 (2003).
14	McCAFFREY et al., "RNA interference in adult mice", Nature, Vol. 418, pp. 38-39 (2002).
15	HASUWA et al., "Small interfering RNA and gene silencing in transgenic mice and rats", FEBS Letters, Vol. 532, pp. 227-230 (2002).

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

